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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/316,163	05/21/1999	WILHELM SCHWAEBLE	3523-P-002	7467

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EXAMINER	
DIBRINO, MARIANNE NMN	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/316,163	SCHWAEBLE ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,5-8,11-19,22,23,26,30-32 and 36* is/are pending in the application.

4a) Of the above claim(s) *5-8 and 11-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,17-19,22,23,26,30-32 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/15/05 has been entered.

Claims 2, 17-19, 22, 23, 26, 30-32 and 36 are currently being examined.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 2, 17-19, 22, 23, 26, 31, 32 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuhn et al (Eur. J. Immunol. 1996, 26/10, 2383-2387, of record) as evidenced by and admissions in the specification on page 15 at lines 4-5 and the paragraph spanning pages 2-3.

Kuhn et al teach that human factor H-like protein 1 (FHL-1) is composed of seven SCR that ***are identical in sequence to those of human factor*** H. Kuhn et al teach that DAF activity resides, *i.e.,* is essential and sufficient for complement activation inhibiting activity, in the first four SCR, *i.e.* SCR 1-4 of both FHL-1 and factor H, and Kuhn et al teach the protein that consists of SCR 1-4 (see entire article, especially last paragraph on page 2383, abstract, section 2.4 on page 2384, section 3.2 on page 2385, discussion).

The admission in the specification on page 15 at lines 4-5 is that SEQ ID NO: 9 is human factor H SCR 1-4. The admissions in the specification on pages 2-3 at the spanning paragraph is that FHp43 is a human factor H glycoprotein and that CCP or complement control protein modules are short consensus repeats or SCRs.

With regard to instant claim 22 and dependent claims 23 and 32, the recitation of intended use in base claim 22 carries no patentable weight in these product claims.

4. Claims 2, 17-19, 22, 23, 26, 31, 32 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon et al (J. Immunol. 1995, 155: 348-356) as evidenced by and admissions in the specification on page 15 at lines 4-5 and the paragraph spanning pages 2-3.

Gordon et al teach a protein consisting of SCR 1-4 of human factor H is essential for full complement activation inhibiting activity, human factor H being a 155 kDa glycoprotein composed of SCR that are approximately 60 amino acid residues in length (see entire article, especially abstract, , introduction, last paragraph on page 350, paragraph spanning pages 354-355).

The admission in the specification on page 15 at lines 4-5 is that SEQ ID NO: 9 is human factor H SCR 1-4. The admissions in the specification on pages 2-3 at the spanning paragraph is that FHp43 is a human factor H glycoprotein and that CCP or complement control protein modules are short consensus repeats or SCRs of approximately 60 amino acid residues and that the factor H protein is 155 kDa.

With regard to instant claim 22 and dependent claims 23 and 32, the recitation of intended use in base claim 22 carries no patentable weight in these product claims.

5. Claims 2, 17-19, 22, 23, 26, 31, 32 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuhn et al (J. Immunol. 1995, 155: 5663-5670) as evidenced by Kuhn et al (Eur. J. Immunol. 1996, 26/10, 2383-2387, of record) and admissions in the specification on page 15 at lines 4-5 and the paragraph spanning pages 2-3.

Kuhn et al teach a protein consisting of SCR 1-4 of human factor H-like protein (see entire article, especially abstract and introduction and first full paragraph on page 5669).

Evidentiary reference Kuhn et al teach that human factor H-like protein 1 (FHL-1) is composed of seven SCR that ***are identical in sequence to those of human factor*** H. Kuhn et al teach that DAF activity resides, *i.e.,* is essential and sufficient for complement activation inhibiting activity, in the first four SCR, *i.e.* SCR 1-4 of both FHL-1 and factor H, and Kuhn et al teach the protein that consists of SCR 1-4 (see entire article, especially last paragraph on page 2383, abstract, section 2.4 on page 2384, section 3.2 on page 2385, discussion).

The admission in the specification on page 15 at lines 4-5 is that SEQ ID NO: 9 is human factor H SCR 1-4. The admissions in the specification on pages 2-3 at the spanning paragraph is that FHp43 is a human factor H glycoprotein and that CCP or complement control protein modules are short consensus repeats or SCRs.

With regard to instant claim 22 and dependent claims 23 and 32, the recitation of intended use in base claim 22 carries no patentable weight in these product claims.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhn et al (Eur. J. Immunol. 1996, 26/10, 2383-2387) or Gordon et al (J. Immunol. 1995, 155: 348-356) or Kuhn et al (J. Immunol. 1995, 155: 5663-5670) in view of Rimpoche et al (Applicant's IDS reference "A", of record) and admissions in the specification on page 15 at lines 4-5 and the paragraph spanning pages 2-3.

Kuhn et al (Eur. J. Immunol) teach that human factor H-like protein 1 (FHL-1) is composed of seven SCR that are identical in sequence to those of human factor H. Kuhn et al teach that DAF activity resides, i.e., essential and sufficient for activity, in the first four SCR, i.e. SCR 1-4 of both FHL-1 and factor H. Kuhn et al teach that factor H was more efficient in decay acceleration than factor FHL-1 in that about 100-fold less protein was required for a 50% inhibition of activity.

Gordon et al teach a protein consisting of SCR 1-4 of human factor H is essential for full complement activation inhibiting activity, human factor H being a 155 kDa glycoprotein composed of SCR that are approximately 60 amino acid residues in length (see entire article, especially abstract, , introduction, last paragraph on page 350, paragraph spanning pages 354-355).

Kuhn et al (J. Immunol.) teach a protein consisting of SCR 1-4 of human factor H-like protein (see entire article, especially abstract and introduction and first full paragraph on page 5669).

Kuhn et al, or Gordon et al, or Kuhn et al do not teach wherein the SCR 1-4 is coupled to artificial membranes as recited in instant claim 30.

Rimpoche et al teach full length *and C-terminal truncated forms of factor H*, including a Mr 36,520 truncated form with complement activation inhibiting activity. Rimpoche et al teach that the full length protein is 155 kDa and is comprised of SCRs of approximately 60 amino acid residues. Rimpoche et al teach factor H coupled to a chromatographic medium, i.e., an artificial membrane. Rimpoche et al teach testing of reactivity of antibodies with the immobilized factor H.

The admission in the specification on page 15 at lines 4-5 is that SEQ ID NO: 9 is human factor H SCR 1-4. The admissions in the specification on pages 2-3 at the spanning paragraph is that FHp43 is a human factor H glycoprotein and that CCP or

complement control protein modules are short consensus repeats or SCRs of approximately 60 amino acid residues and that the factor H protein is 155 kDa (see entire article, especially abstract, introduction, paragraph spanning pages 599-600, discussion).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have coupled the SCR 1-4 taught by Kuhn et al or Gordon et al or Kuhn et al taught to a chromatographic medium as taught by Rimpoche et al.

One of ordinary skill in the art would have been motivated to do this in order to test antibodies to SCR 1-4 as taught by Rimpoche et al for the full length and truncated forms of factor H taught by Rimpoche et al. With regard to instant claim 30, the recitation of a method wherein the claimed product is made, i.e., how it is coupled, carries no patentable weight in this product claim.

Applicant's arguments in the amendment filed 6/15/05 have been fully considered, but are not persuasive.

Applicant's arguments are of record in the said amendment on pages 5-8, briefly that: (1) Kuhn et al does not teach a molecule consisting of SCR 1-4 of complement factor H, (2) the focus of Ripoche et al is on the entire sequence of factor H, not on discrete constituents, (3) neither reference alone or in combination suggests that complement control modules of Applicant's invention are even identified or that the truncated protein modules would provide enhanced cofactor activity as demonstrated by Applicant, (4) neither teach or suggest which amino acid residues correspond to CCP 1-4, (5) SEQ ID NO: 9 is shorter than would be expected than would be assumed from Ripoche et al, (6) Kuhn et al state that factor H, not truncated factor H, was more efficient in decay acceleration, and (7) FHL-1 and Ripoche et al is directed to the entire factor H sequence, and Applicant's recombinant factor H is about 10-1000 fold more potent.

It is the Examiner's position that: (1) Kuhn et al does teach a molecule consisting of SCR 1-4 of complement factor H as enunciated in the instant rejection, (2 and 3) Ripoche et al teach truncated versions of factor H that possess complement activation inhibiting ability as enunciated in the instant rejection, and Kuhn et al or Gordon et al or Kuhn et al teach SCR 1-4 has complement activation inhibition ability, (4) Kuhn et al or Gordon et al or Kuhn et al teach CCPs of the instant claims as evidenced by the cited admissions in the specifications in the instant rejection and the primary references each teach activity of these CCP or SCR 1-4, (5) regardless of what Ripoche et al teach in comparison with Applicant's SEQ ID NO: 9, (6) Kuhn et al or Gordon et al or Kuhn et al is relied upon for teaching a truncated version of factor H consisting of CCP or SCR 1-4 identical to that of the instant claims that has complement activating inhibition activity and Ripoche et al is relied upon for the teaching of coupling factor H to a chromatographic medium and testing of factor H for reactivity with factor H specific

antibodies, and (7) since the primary references teach the SCR 1-4 of factor H, the motivation to make SCR 1-4 is not required in the instant rejection, and as a side issue, Kuhn et al teach that FH is about 100 times more efficient than FHL-1, the said difference being explained by an additional binding site located within SCR 8-20, a domain unique to FH.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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